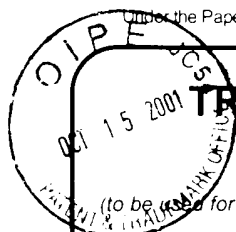


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Filing Date January 4, 2001

First Named Inventor Kapikian, Albert H.

Group Art Unit 1653

Examiner Name Unassigned

Total Number of Pages in This Submission

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Attorney Docket Number 015280341100

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☒ Information Disclosure Statement

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Brian W. Poor

Reg No. 32,928

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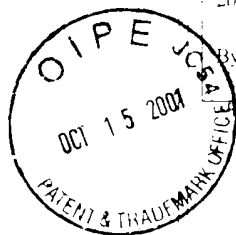
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PATENT

Attorney Docket No.: 015280-341100US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

ALBERT Z. KAPIKIAN et al.

Application No.: 09/743,338

Filed: January 4, 2001

For: MULTIVALENT HUMAN-BOVINE ROTAVIRUS VACCINE

Examiner: Unassigned

Art Unit: 1653

**INFORMATION DISCLOSURE
STATEMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

The references cited on attached form PTO-1449 are being called to the attention of the Examiner. Copies of the references are enclosed. Also enclosed is a copy of the Search/Examination report corresponding to the PCT application. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

The following U.S. Patent is set forth below by issue date.

AA 4,571,385 02 18 86 Greenberg et al.

The following articles are set forth by the indicated year of publication date:

AB Woode et al., "The Isolation of a Reovirus-Like Agent Associated with Diarrhoea in Colostrum-Deprived Calves in Great Britain," *Research in Veterinary Science* 16:102-105 (1974)

AC Bridger and Woode, "Neonatal Calf Diarrhoea: Identification of a Reovirus-Like (Rotavirus) Agent in Faeces By Immunofluorescence and Immune Electron Microscopy," *The British Veterinary Journal* 131:528-535 (1975)

AD Banatvala et al., "Rotaviral Infections in Human Neonates," *The Journal of the American Veterinary Association* 173:527-530 (1978)

AE Wyatt et al., "Reovirus-like Agents (Rotaviruses) Associated with Diarrheal Illness in Animals and Man," *Perspectives in Virology* 10:121-145 (1978)

AF Wyatt et al., "Human Rotavirus Type 2: Cultivation in vitro," *Science* 207:189-191 (1980)

AG Vesikari et al., "Immunogenicity and Safety of Live Oral Attenuated Bovine Rotavirus Vaccine Strain RIT 4237 in Adults and Young Children," *Lancet* 2:807-811 (1983)

AH Hoshino et al., "Serotypic Characterization of Rotaviruses Derived from Asymptomatic Human Neonatal Infections," *Journal of Clinical Microbiology* 21:425-430 (1985)

AI Kapikian et al., "Rhesus Rotavirus: A Candidate Vaccine for Prevention of Human Rotavirus Disease," *Vaccines* 85, Lerner et al., eds., Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, pp. 357-367 (1985)

AJ Midthun et al., "Reassortant Rotaviruses as Potential Live Rotavirus Vaccine Candidates," *Journal of Virology* 53:949-954 (1985)

AK Vesikari et al., "Dose-Response Study of RIT 4237 Oral Rotavirus Vaccine in Breast-Fed and Formula-Fed Infants," *Pediatric Infectious Diseases* 4:622-625 (1985)

AL Clark et al., "Immune Response of Infants and Children to Low-Passage Bovine Rotavirus (Strain WC3), " *The American Journal of Diseases of Children* 140:350-356 (1986)

AM Midthun et al., "Single Gene Substitution Rotavirus Reassortants Containing the Major Neutralization Protein (VP7) of Human Rotavirus Serotype 4," *Journal of Clinical Microbiology* 24:822-826 (1986)

AN Vesikari et al., "A Comparative Trial of Rhesus Monkey (RRV-1) and Bovine (RIT 4237) Oral Rotavirus Vaccines in Young Children," *The Journal of Infectious Diseases* 153:832-839 (1986)

AO Halsey et al., "Human-Rhesus Reassortant Rotavirus Vaccines: Safety and Immunogenicity in Adults, Infants, and Children," *The Journal of Infectious Diseases* 158:1261-1267 (1988)

AP Kapikian et al., "Development of a Rotavirus Vaccine by a "Jennerian" and a Modified "Jennerian" Approach," Vaccines 88, Chanock et al., eds., Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, pp. 151-159 (1988)

AQ Flores et al., "Reactions to and Antigenicity of Two Human-Rhesus Rotavirus Reassortant Vaccine Candidates of Serotypes 1 and 2 in Venezuelan Infants," *Journal of Clinical Microbiology* 27:512-518 (1989)

AR Midthun et al., "Comparison of Immunoglobulin A (IgA), IgG, and IgM Enzyme-linked Immunosorbent Assays, Plaque Reduction Neutralization Assay, and Complement Fixation in Detecting Seroresponses to Rotavirus Vaccine Candidates," *Journal of Clinical Microbiology* 27:2799-2804 (1989)

AS Bernstein et al., "Evaluation of WC3 Rotavirus Vaccine and Correlates of Protection in Healthy Infants," *The Journal of Infectious Diseases* 162:1055-1062 (1990)

AT Clark et al., "Immune Protection of Infants against Rotavirus Gastroenteritis by a Serotype 1 Reassortant of Bovine Rotavirus WC3," *The Journal of Infectious Diseases* 161:1099-1104 (1990)

AU Clark et al., "Serotype 1 Reassortant of Bovine Rotavirus WC3, Strain W179-9, Induces a Polytypic Antibody Response in Infants," *Vaccine* 8:327-332 (1990)

AV Flores et al., "Comparison of Reactogenicity and Antigenicity of M37 Rotavirus Vaccine and Rhesus-Rotavirus-Based Quadrivalent Vaccine," *Lancet* 336:330-334 (1990)

AW Green et al., "Homotypic and Heterotypic Epitope-Specific Antibody Responses in Adult and Infant Rotavirus Vaccines: Implications for Vaccine Development," *The Journal of Infectious Diseases* 161:667-679 (1990)

AX Nakagomi et al., "Isolation and Molecular Characterization of a Serotype 9 Human Rotavirus Strain," *Microbiology and Immunology* 34:77-82 (1990)

AY Perez-Schael et al., "Clinical Studies of a Quadrivalent Rotavirus Vaccine in Venezuelan Infants," *Journal of Clinical Microbiology* 28:553-558 (1990)

AZ Taniguchi et al., "Antibody Response to Serotype-Specific and Cross-Reactive Neutralization Epitopes on VP4 and VP7 after Rotavirus Infection or Vaccination," *Journal of Clinical Microbiology* 29:483-487 (1991)

BA Kapikian et al. "An Update on the "Jennerian" and Modified "Jennerian" Approach to Vaccination of Infants and Young Children against Rotavirus Diarrhea," *Advances in Experimental Medicine and Biology* 327:59-69 (1992)

BB Madore et al., "Field Trial of Rhesus Rotavirus or Human-Rhesus Rotavirus Reassortant Vaccine of VP7 Serotype 3 or 1 Specificity in Infants," *The Journal of Infectious Diseases* 166:235-243 (1992)

BC Christy et al., "Evaluation of a Bovine-Human Rotavirus Reassortant Vaccine in Infants," *The Journal of Infectious Diseases* 168:1598-1599 (1993)

BD Flores et al., "Reactogenicity and Immunogenicity of a High-Titer Rhesus Rotavirus-Based Quadrivalent Rotavirus Vaccine," *Journal of Clinical Microbiology* 31:2439-2445 (1993)

BE Vesikari, "Clinical Trials of Live Oral Rotavirus Vaccines: the Finnish Experience," *Vaccine* 11:255-261 (1993)

BF Simasathien et al., "Vaccination of Thai Infants with Rhesus-Human Reassortant Tetraivalent Oral Rotavirus Vaccine," *The Pediatric Infectious Disease Journal* 13:590-596 (1994)

BG Vesikari, "Bovine Rotavirus-Based Rotavirus Vaccines in Humans," *Viral Infections of the Gastrointestinal Tract*, Kapikian, ed., Marcel Dekker, Inc., New York pp. 419-442 (1994)

BH Kapikian, "Rhesus Rotavirus-Based Human Rotavirus Vaccines and Observations on Selected Non-Jennerian Approaches to Rotavirus Vaccination," *Viral Infections of the Gastrointestinal Tract*, Kapikian, ed., Marcel Dekker, Inc., New York pp. 443-470 (1994)

BI Bernstein et al., "Evaluation of Rhesus Rotavirus Monovalent and Tetraivalent Reassortant Vaccines in US Children," *Journal of the American Medical Association* 273:1191-1196 (1995)

BJ Treanor et al., "Evaluation of the Protective Efficacy of a Serotype 1 Bovine-Human Rotavirus Reassortant Vaccine in Infants," *The Pediatric Infectious Disease Journal* 14:301-307 (1995)

BK Clark et al., "The Development of Multivalent Bovine Rotavirus (Strain WC3) Reassortant Vaccine for Infants," *The Journal of Infectious Diseases* 174 (suppl.) 1:S73-80 (1996)

BL Clark et al., "WC3 Reassortant Vaccines in Children," *Archives of Virology* (suppl.) 12:187-198 (1996)

BM Kapikian et al., "Efficacy of a Quadrivalent Rhesus Rotavirus-Based Human Rotavirus Vaccine Aimed at Preventing Severe Rotavirus Diarrhea in Infants and Young Children," *The Journal of Infectious Diseases* 174 (Suppl. 1): S65-72 (1996)

BN Midthun et al., "Rotavirus Vaccines: an Overview," *Clinical Microbiology Reviews* 9:423-434 (1996)

BO Rennels et al., "Safety and Efficacy of High-Dose Rhesus-Human Reassortant Rotavirus Vaccines-Report of the National Multicenter Trial," *Pediatrics* 97:7-13 (1996)

BP Vesikari et al., "Trials of Oral Bovine and Rhesus Rotavirus Vaccines in Finland: a Historical Account and Present Status," *Archives of Virology* (suppl.) 12:177-186 (1996)

BQ Hoshino et al., "Construction of Four Double Gene Substitution Human x Bovine Rotavirus Reassortant Vaccine Candidates: Each Bears Two Outer Capsid Human Rotavirus Genes, One Encoding P Serotype 1A and the Other Encoding G Serotype 1, 2, 3, or 4 Specificity," *Journal of Medical Virology* 51:319-325 (1997)

BR Joensuu et al., "Randomized Placebo-Controlled Trial of Rhesus-Human Reassortant Rotavirus Vaccine for Prevention of Severe Rotavirus Gastroenteritis," *Lancet* 350:1205-1209 (1997)

BS Timenetsky et al., "A Novel Human Rotavirus Serotype with Dual G5-G11 Specificity," *Journal of General Virology* 78:1373-1378 (1997)

BT Clements-Mann et al., "Safety and Immunogenicity of Live Attenuated Human-Bovine (UK) Reassortant Rotavirus Vaccines with VP7-specificity for Serotypes 1, 2, 3 or 4 in Adults, Children and Infants," *Vaccine* 17:2715-2725 (1999)

Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Dated: February 2001

By: Brian W. Poor
Brian W. Poor
Reg. No. 32,928

ALBERT Z. KAPIKIAN et al.
Application No.: 09 743,338
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